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X-Ray Devices used for Diagnosis and Therapy

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X-Ray Devices used for Diagnosis and Therapy

Sec. 19-25d-1. Scope

Sections 19-24-2 to 19-24-11, inclusive, establish special requirements for diagnostic and therapeutic x-ray installations. The provisions of said sections are in addition to and not in substitution for other applicable sections of these regulations.

(Effective October 1, 1982)

Sec. 19-25d-2. Definitions

As used in sections 19-25d-2 to 19-25d-11, inclusive:

“Aluminum equivalent” means the thickness of aluminum affording the same attenuation, under specified conditions, as the material in question.

“Dead-man switch” means a switch so constructed that a circuit-closing contact can only be maintained by continuous pressure by the operator.

“Diagnostic-type tube housing” means an x-ray tube housing so constructed that the leakage radiation at a distance of one meter from the target cannot exceed one hundred milliroentgens in one hour when the tube is operated at any of its specified ratings.

“Filter” means material placed in the useful beam to absorb preferentially the less penetrating radiations.

“Half-value layer (hvl)” means the thickness of an absorber required to reduce a beam or radiation to one-half its incident exposure dose rate.

“Inherent filtration” means the filtration in the useful beam due to the window of the x-ray tube and any permanent tube enclosure.

“Interlock” means a device for precluding access to an area of radiation hazard either by preventing entry or by automatically removing the hazard.

“Kilovolts peak (kvp)” means the crest value in kilovolts of the potential of a pulsating potential generator. When only one-half of the wave is used, the value refers to the useful half of the wave.

“Lead equivalent” means the thickness of lead affording the same attenuation, under specified conditions, as the material in question.

“Leakage radiation” means all radiation coming from within the tube housing except the useful beam.

“Owner” means a person or organization owning or having by law the actual control of the x-ray device or devices.

“Primary protective barrier” means a barrier sufficient to attenuate the useful beam.

“Protective apron” means an apron made of attenuating materials, used to reduce radiation exposure.

“Protective barrier” means a barrier of attenuating materials, used to reduce radiation exposure.

“Protective glove” means a glove made of attenuating materials, used to reduce radiation exposure.

“Scattered radiation” means radiation that, during passage through matter, has been deviated in direction.

“Secondary protective barrier” means a barrier sufficient to attenuate stray radiation.

“Shutter” means a device, generally of lead, fixed to an x-ray tube housing to intercept useful beam.

“Stray radiation” means radiation not serving any useful purpose. It includes leakage and secondary radiation.

“Therapeutic-type tube housing” means an x-ray tube housing so constructed that the leakage radiation at a distance of one meter from the target cannot exceed one roentgen in one hour; and at a distance of five centimeters from any point on the surface of the housing accessible to the patient cannot exceed thirty roentgens in one hour when the tube is operated at any of its specified ratings.

“Useful beam” means that part of the radiation which passes through the window, aperture, cone or other collimating device of the tube housing.

(Effective October 1, 1982)

Sec. 19-25d-3. General safety provisions

(a) **Equipment.** No person shall make, sell, lease, transfer, lend or install x-ray or fluoroscopic equipment or the supplies used in connection with such equipment unless such supplies and equipment, when properly placed in operation and properly used, will meet the requirements of sections 19-25d-3 to 19-25d-11, inclusive. This includes responsibilities for the delivery of cones or collimators, filters, adequate timers and fluoroscopic shutters, where applicable.

(b) **Use**

(1) The owner shall be responsible for assuring that all requirements of sections 19-25d-3 to 19-25d-11, inclusive, are met.

(2) The owner shall assure that all x-ray equipment under his control is operated only by individuals adequately instructed in safe operating procedures and competent in safe use of the equipment.

(c) **Shielding**

(1) Each installation shall be provided with primary barriers and/or secondary barriers of such thickness as are computed in accordance with Appendix C, National Bureau of Standards Handbook 76: “Medical X-ray Protection Up to Three Million Volts,” or any official revision of or subsequent replacement for this handbook, a copy of which is on file in the state department of environmental protection, state office building, Hartford.

(2) Lead barriers shall be mounted in such a manner that they will not sag or cold-flow because of their own weight and shall be protected against mechanical damage.

(3) Joints between different kinds of protective materials shall be so designed that the over-all protection of the barrier is not impaired.

(4) Joints at the floor and ceiling shall be so designed that the over-all protection is not impaired.

(5) Windows, window frames, doors and door frames shall have the same lead equivalent as that required of the adjacent wall.

(6) Holes in protective barriers shall be covered so that overall attenuation is not impaired.

(d) The commissioner may grant a variance to requirements in Sections 19-25d-3 to 19-25d-11 inclusive, provided that it can be demonstrated that the use of the equipment under the variance will not result in an increase in radiation exposure to the patient or operator.

(Effective October 1, 1982)

Sec. 19-25d-4. Fluoroscopic installations

(a) **Equipment**

(1) The tube housing shall be of diagnostic type.

(2) The target-to-panel or target-to-table top distance of equipment installed before January 1, 1965, shall not be less than twelve inches, and shall not be less than fifteen inches in equipment installed or reinstalled thereafter.

(3) The total filtration permanently in the useful beam shall not be less than two and one-half millimeters aluminum equivalent. This requirement may be assumed to have been met if the half-value layer is not less than two and one-half millimeters aluminum at normal operating voltages.

(4) The equipment shall be so constructed that the entire cross-section of the useful beam is attenuated by a primary barrier. This barrier is usually the viewing device, either a conventional fluoroscopic screen or an image intensification mechanism.

(A) (i) For equipment installed before January 1, 1965, the required lead equivalent of the barrier shall not be less than one and one-half millimeters for one hundred kvp, shall not be less than one and eight-tenths millimeters for one hundred twenty-five kvp, or shall not be less than two millimeters for one hundred fifty kvp.

(ii) For equipment installed or reinstalled after January 1, 1965, the required lead equivalent of the barrier shall not be less than two millimeters for one hundred kvp, shall not be less than two and four-tenths millimeters for one hundred twenty-five kvp, or shall not be less than two and seven-tenths millimeters for one hundred fifty kvp.

(iii) Insofar as related to the provisions of subparagraphs (A) (i) and (A) (ii) of the subdivision for conventional fluoroscopes these requirements may be assumed to have been met if the exposure dose rate measured at the viewing surface of the fluorescent screen does not exceed fifty milliroentgens per hour with the screen in the primary beam of the fluoroscope without a patient, under normal operating conditions.

(B) Collimators shall be provided to restrict the size of the useful beam to less than the area of the barrier. For conventional fluoroscopes this requirement is met if, when the adjustable diaphragm is opened to its fullest extent, an unilluminated margin is left on the fluorescent screen with the screen centered in the beam at a distance of thirty-five centimeters (fourteen inches) from the panel or table top. The margin requirement does not apply to installations where image intensifiers are used, but a protective shield shall be provided in these installations so that the useful beam does not produce a radiation hazard.

(C) The tube mounting and the barrier shall be so linked together that, under conditions of normal use, the barrier always intercepts the useful beam.

(D) Collimators and adjustable diaphragms or shutters to restrict the size of the useful beam shall provide a minimum of two millimeters lead-equivalent protection for one hundred kvp, two and four-tenths millimeters for one hundred twenty-five kvp or two and seven-tenths millimeters for one hundred fifty kvp.

(5) The exposure switch shall be of the dead-man type.

(6) A manual-reset, cumulative timing device shall be used which will either indicate elapsed time by an audible signal or turn off the apparatus when the total exposure exceeds a predetermined limit in one or a series of exposures.

(7) For routine fluoroscopy, the exposure rate measured at the panel or table top should be as low as practicable and shall not exceed ten roentgens per minute.

(8) Mobile fluoroscopic equipment shall meet the requirements of this section where applicable, except that:

(A) In the absence of a table top, a cone or spacer frame shall limit the target-to-skin distance to not less than twelve inches.

(B) Image intensification shall always be provided. Conventional fluoroscopic screens shall not be used.

(C) It shall be impossible to operate a machine when the collimating cone or diaphragm is not in place.

(D) A maximum permissible dose rate of ten roentgens per minute shall be measured at the minimum target-to-skin distance.

(b) **Structural shielding.** Ordinarily, only secondary barriers are necessary except for combined fluoroscopic-radiographic installations.

(Effective October 1, 1982)

Sec. 19-25d-5. Radiographic installation other than dental and veterinary medicine

(a) Equipment

(1) The tube housing shall be of diagnostic type.

(2) Diaphragms or cones capable of restricting the beam to the area of clinical interest shall be provided for collimating the useful beam and shall provide the same degree of protection as is required of the housing.

(3) (A) Except when contraindicated for a particular medical purpose, for equipment operating at seventy kvp and below, the total filtration permanently in the useful beam shall be equivalent to at least one and one-half mm of aluminum. This requirement may be assumed to have been met if the half-value layer is not less than one and one-half mm aluminum at normal operating voltages.

(B) Except when contraindicated for a particular medical purpose, for equipment capable of operating above seventy kvp, the total filtration permanently in the useful beam shall be equivalent to at least two and one-half value layer is not less than two and one-half mm aluminum at normal operating voltages.

(4) A device shall be provided to terminate the exposure after a preset time or exposure.

(5) A dead-man type of exposure switch shall be so arranged that it cannot be conveniently operated outside a shielded area. Exposure switches for "spot film" devices used in conjunction with fluoroscopic tables are excepted from this shielding requirement.

(b) Structural shielding

(1) All wall, floor and ceiling areas exposed to the useful beam shall have primary barriers. Primary barriers in walls shall extend to a minimum height of eighty-four inches above the floor.

(2) Secondary barriers shall be provided in all wall, floor and ceiling areas not having primary barriers or where the primary barrier requirements are lower than the secondary barrier requirements.

(3) The operator's station at the control shall be behind a protective barrier, either in a separate room, in a protected booth, or behind a shield which will intercept the useful beam and any radiation which has been scattered only once.

(4) A window of lead-equivalent glass equal to that required by the adjacent barrier or a mirror system shall be provided large enough and so placed that the operator can see the patient without having to leave the protected area during exposure.

(c) Operating procedures

(1) No individual occupationally exposed to radiation shall be permitted to hold patients during exposures except during emergencies, nor shall any individual be regularly used for this service.

(2) Only individuals required for the radiographic procedure shall be in the radiographic room during exposure; and, except for the patient, no unprotected parts of their bodies shall be in the useful beam.

- (3) The useful beam shall be restricted to an area of clinical interest.
(Effective October 1, 1982)

Sec. 19-25d-6. Special requirements for mobile diagnostic radiographic equipment

(a) Equipment

- (1) All requirements of section 19-25d-5 apply except subdivision (a) (5).
(2) The exposure control switch shall be of the dead-man type and shall be so arranged that the operator can stand at least six feet from the patient and well away from the useful beam.

(b) **Structural shielding** When a mobile unit is used routinely in one location, it shall be considered a fixed installation subject to the shielding requirements specified in sections 19-25d-3 (c) and 19-25d-5 (b).

(c) Operating procedures

- (1) All provisions of subsection 19-25d-5 (c) apply except subdivision (2).
(2) The target-to-skin distance shall be not less than twelve inches.
(3) Personnel monitoring shall be required for all individuals operating mobile x-ray equipment.

(Effective October 1, 1982)

Sec. 19-25d-7. Special requirements for chest photofluorographic installations

(a) Equipment

- (1) All provisions of subsection 19-25d-2 (a) apply.
(2) A collimator shall restrict the useful beam to the area of the photofluorographic screen.

(b) **Structural shielding.** All provisions of subsections 19-25d-3 and 19-25d-5 (b) apply.

(c) Operating procedures

- (1) All provisions of subsection 19-25d-5 (c) apply.
(2) All individuals except the patient being examined shall be in shielded positions during exposures.
(3) Personnel monitoring shall be required for all individuals operating the equipment.

(Effective October 1, 1982)

Sec. 19-25d-8. Dental radiographic installations

(a) Equipment

- (1) The tube housing shall be of diagnostic type.
(2) Diaphragms or cones shall be used for collimating the useful beam and shall provide the same degree of protection as the housing. The diameter of the useful beam at the cone tip shall not be more than three inches (for intra-oral radiography).

(3) A cone or spacer frame shall provide a target-to-skin distance of not less than seven inches with apparatus operating above fifty kvp or four inches with apparatus operating at fifty kvp or below.

(4) (A) For equipment operating up to seventy kvp, the total filtration permanently in the useful beam shall be equivalent to at least one and one-half mm of aluminum. This requirement may be assumed to have been met if the half value layer is not less than one and one-half mm aluminum at normal operating voltages.

(B) For equipment operating above seventy kvp, the total filtration permanently in the useful beam shall be equivalent to at least two and one-half mm of aluminum.

This requirement may be assumed to have been met if the half-value layer is not less than two and one-half mm aluminum at the normal operating voltages.

(5) A device shall be provided to terminate the exposure after a preset time or exposure.

(6) The exposure control switch shall be of the dead-man type.

(7) Each installation shall be provided with a protective barrier for the operator or shall be so arranged that the operator can stand at least six feet from the patient and well away from the useful beam.

(b) Structural shielding

(1) Dental rooms containing x-ray machines shall be provided with primary barriers at all areas struck by the useful beam. Consideration shall be given to the attenuation provided by the patient.

(2) When dental x-ray units are installed in adjacent rooms or areas, protective barriers shall be provided between the rooms or areas. Note: In many cases structural materials of ordinary walls suffice as a protective barrier without addition of special shielding material.

(c) Operating procedures

(1) Neither the dentist nor his assistant shall be permitted to hold patients or films during exposure, nor shall any individuals be regularly used for this service.

(2) During each exposure, the operator shall stand at least six feet from the patient or behind a protective barrier.

(3) Only the patient shall be in the useful beam.

(4) Neither the tube housing nor the pointer cone shall be hand-held during exposure.

(5) Hand-held fluoroscopes shall not be used in dental examinations.

(Effective October 1, 1982)

Sec. 19-25d-9. Therapeutic x-ray installations

(a) Equipment

(1) The tube housing shall be of therapeutic type.

(2) Permanent diaphragms or cones used for collimating the useful beam shall afford the same degree of protection as the tube housing. Adjustable or removable beam-defining diaphragms or cones shall transmit not more than five percent of the useful beam obtained at the maximum kilovoltage and with maximum treatment filter.

(3) Filters shall be secured in place to prevent them from dropping out during treatment. The filter slot shall be so constructed that the radiation escaping through it does not exceed one roentgen per hour at one meter, or, if the radiation from the slot is accessible to the patient, thirty roentgens per hour at five centimeters from the external opening.

(4) The x-ray tube shall be so mounted that it cannot turn or slide with respect to the aperture.

(5) Means shall be provided to immobilize the tube housing during stationary portal treatment.

(6) A timer shall be provided to terminate the exposure after a preset time regardless of what other exposure limiting devices are present.

(7) Equipment utilizing shutters to control the useful beam shall have a shutter position indicator on the control.

(8) There shall be on the control panel an easily discernible indicator which will give positive information as to whether or not the x-ray tube is energized.

(b) Structural shielding

(1) All wall, floor and ceiling areas that can be struck by the useful beam, plus a border of one foot, shall be provided with primary protective barriers.

(2) All wall, floor and ceiling areas that, because of restrictions in the orientation of the useful beam, cannot be struck by the useful beam shall be provided with secondary barriers.

(3) With equipment operating above one hundred twenty-five kvp, the required barriers shall be an integral part of the building.

(4) With equipment operating above one hundred fifty kvp, the control station shall be within a protective booth or outside the treatment room.

(5) Interlocks shall be provided so that when any door of the treatment room is opened either the machine will shut off automatically or the radiation level within the room will be reduced to an average of not more than two milliroentgens per hour and a maximum of ten milliroentgens per hour at a distance of one meter in any direction from the target. After such shut off or reduction in output, it shall be possible to restore the machine to full operation only from the control panel.

(6) Provision shall be made to permit continuous observation of patients during irradiation.

(7) Windows, mirror systems or closed-circuit television viewing screens used for observing the patient shall be so located that the operator may see the patient and the control panel from the same position.

(c) Operating procedures

(1) All new installations, and existing installations not previously surveyed, shall have a protection survey made by, or under the direction of, a qualified expert. This shall also be done after any change in the installation which might produce a radiation hazard. The expert shall report his findings in writing to the person in charge of the installation.

(2) The installation shall be operated in compliance with any limitations indicated by the protection survey.

(3) No individual who works with radiation, unless he is the patient, shall be in the treatment room during exposure. No other individual shall be there except when it is clinically necessary. If an individual is required to be in the treatment room with the patient during exposure, he shall be protected as much as possible from scattered radiation and shall not be in the useful beam.

(Effective October 1, 1982)

Sec. 19-25d-10. Special requirements for x-ray therapy equipment operated at potentials of sixty kv and below**(a) Equipment**

(1) All provisions of section 19-25d-9 (a) apply except, for equipment used for "contact therapy," subdivision (1) in which instance the leakage radiation at the surface of the tube housing shall not exceed one-tenth roentgen per hour.

(2) There shall be on the control panel some easily discernible device which will give positive information as to whether or not the tube is energized.

(b) Operating procedures

(1) Automatic timers shall be provided which will permit accurate presetting and determination of exposures as short as one second.

(2) In the therapeutic application of apparatus constructed with beryllium or other low-filtration windows, the owner shall insure that the unfiltered radiation reaches only the part intended and that the useful beam is blocked at all times except when actually being used.

(3) Machines having an output of more than one thousand roentgens per minute at any accessible place shall not be left unattended without the power being shut off at the primary disconnecting means.

(4) If the tube is hand-held during irradiation, the operator shall wear protective gloves and aprons.

(Effective October 1, 1982)

Sec. 19-25d-11. Veterinary medicine radiographic installations

(a) Equipment

(1) The tube housing shall be of diagnostic type.

(2) Diaphragms or cones shall be provided for collimating the useful beam to the area of clinical interest and shall provide the same degree of protection as is required of the housing.

(3) Except when contraindicated for a particular radiographic purpose, the total filtration permanently in the useful beam shall not be less than one and one-half millimeters aluminum-equivalent for equipment operating up to seventy kvp and two millimeters aluminum-equivalent for machines operated in excess of seventy kvp.

(4) A device shall provided to terminate the exposure after a preset time or exposure.

(5) A dead-man type of exposure switch shall be provided, together with an electrical cord of sufficient length so that the operator can stand out of the useful beam and at least six feet from the animal during all x-ray exposures.

(b) **Structural shielding.** All wall, ceiling and floor areas shall be equivalent to or provided with applicable protective barriers as required in section 19-25d-5 (b).

(c) Operating procedures

(1) The operator shall stand well away from the tube housing and the animal during radiographic exposures. The operator shall not stand in the useful beam. If film must be held, it shall be held by individuals not occupationally exposed to radiation. Hand-held fluoroscopic screens shall not be used. The tube housing shall not be held by the operator. No individuals other than the operator shall be in the x-ray room while exposures are being made unless such person's assistance is required.

(2) In any application in which the operator is not located being a protective barrier, clothing consisting of a protective apron having a lead equivalent of not less than one-half millimeter shall be worn by the operator and any other individuals in the room during exposures.

(3) No individual shall be regularly employed to hold or support animals during radiation exposures. Operating personnel shall not perform this service except in cases in which no other method is available. Any individual holding or supporting an animal during radiation exposure shall wear protective gloves and apron having a lead-equivalent of not less than one-half millimeter.

(Effective October 1, 1982)